

NDC 69238-7033-1

**Fludrocortisone
Acetate Tablets, USP**

0.1 mg

Rx only
100 Tablets



Each tablet contains 0.1 mg fludrocortisone acetate.

USUAL DOSAGE: See accompanying outsert for complete prescribing information.

Warning: Potent drug

This is a bulk package. Dispense in a tightly-closed, light-resistant container as defined in the USP, with a child-resistant closure, as required.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excess heat.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Product of Italy

Rev. 05-2020-01



Non-Varnish Area
(For Lot And Exp. Date)
34 mm x 28 mm

FLUDROCORTISONE ACETATE

fludrocortisone acetate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69238-7033
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUDROCORTISONE ACETATE (UNII: V47IF0PVH4) (FLUDROCORTISONE - UNII:U0476M545B)	FLUDROCORTISONE ACETATE	0.1 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	white (white to off-white)	Score	2 pieces
Shape	ROUND (round, convex tablets)	Size	6mm
Flavor		Imprint Code	7033
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-7033-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2002	
2	NDC:69238-7033-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/18/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040431	03/18/2002	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	analysis(69238-7033) , label(69238-7033) , manufacture(69238-7033) , pack(69238-7033)

Revised: 2/2024

Amneal Pharmaceuticals NY LLC